DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

JUL 27 2015

Pentax Precision Instrument Corporation
Mr. Paul Silva
Regulatory Affairs Coordinator
30 Ramland Road
Orangeburg, NY 10962-2699

Re: K010740
Trade/Device Name: FG-36UX Fiber Ultrasound Gastroscope/
EUB-6000 Ultrasound Diagnostic Scanner
Regulation Number: 21 CFR 892.1550
Regulation Name: Ultrasonic pulsed doppler imaging system
Regulatory Class: II
Product Code: IYN, ODG
Dated (Date on orig SE ltr): March 12, 2001
Received (Date on orig SE ltr): March 13, 2001

Dear Mr. Silva,

This letter corrects our substantially equivalent letter of April 17, 2001.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be

found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Benjamin R. Fisher -S

Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE

System: EUB-6000

Probe: FG-36UX

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows

Clinical Application		Mode of Operation					
General (Track I only)	Specific (Track I & III)	B	M	PWD	CWD	Color Doppler	Amplitude Doppler
Ophthalmic							
Fetal Imaging & Other	Fetal						
	Abdominal						
	Intra-operative (Spec.)						
	Intra-operative (Neuro.)						
	Laproscopic						
	Pediatric						
	Small Organ						
	Neonatal Cephalic						
	Adult Cephalic						
	Trans-rectal						
	Trans-vagina						
	Trans-urethral						
	Trans-esoph. (non-Card.)						
	Musculo-skel. (Convent.)						
	Musculo-skel. (Superfic.)						
	Intra-luminal						
	Endoscopy	N	N	N		N	N
Cardiac	Cardiac Adult						
	Cardiac Pediatric						
	Trans-esophageal (card.)						
	Other (spec.)						
Peripheral Vessel	Peripheral vessel						
	Other (Spec.)						

N = new application: P = previously cleared by FDA: E = added under Appendix E

(Please do not write below this line – continue on another page if needed

Concurrence of CDRH, Office of Device Evaluation (ODE)

Perscription Use (Per 21 CFR 801.109)

(Division Sign-Off)

Division of Reproductive, Abdominal, ENT, and Radiological Devices

510(k) Number K010740

510(k)Summary

FG-36UX, Fiber Ultrasound Gastroscope for use with EUB-6000 Ultrasound Diagnostic Scanner

K010740

Submitter Information:

Pentax Precision Instrument Corporation (PPIC)
30 Ramland Road
Orangeburg, NY, 10962
Tel: (914)-365-0700

APR 1 7 2001

Name Of Device:

Trade Name: FG-36UX, Fiber Ultrasound Gastroscope
Classification Name: Diagnostic Ultrasound Transducer (74JOP) {892.1570}, Endoscope and Accessories (78KOG) {876.1500}

Predicated Device(s) Information:

Model, Description	Manufacturer	PMN#
FG-36UX, Fiber Ultrasound Gastroscope (with EUB-410,-515,-565,-555)	PPIC	K961974
EUB-6000, Ultrasound Diagnostic Scanner	Hitachi America	K994026

Device Description: The FG-36UX, Fiber Ultrasound Gastroscope, can be used with any Lightsource (with the appropriate lightguide receptacle) and must be used with Ultrasound Scanner (software controlled device). The endoscope has a flexible insertion tube, a control body, and Umbilicus . The umbilicus is bifurcated where one connector is connected to the Lightsource and contains connections for air/water and suction. The other umbilicus bifurcation is connected at the ultrasound scanner. The control body includes controls for up/ down/ left/ right angulation, an accessory elevator control, air/water delivery, suction selection/ control, forward water jet port, balloon insulflation, an accessory inlet port, and the endoscopic image viewing occular. The device contains light carrying bundles, one to illuminate the body cavity another to optically visualize the anatomy, and an ultrasound transducer to collect ultrasonic image data. The instrument contains a working channel through which biopsy devices, or other devices, may be introduced (the instrument is supplied with two biopsy forceps). A convex linear array transducer delivers ultrasonic pulses, reflections of the pulses are received and signals are passed to the Ultrasound Scanner for display. The instrument is immersable (with the use of supplied cleaning accessories) except for the Ultrasound Scanner Connector (as described in the Endoscope operator Manual cleaning instructions).

Intended Use: The FG-36UX, Fiber Ultrasound Gastroscope, is intended to provide optical visualization of, ultrasonic visualization of, and therapeutic access to, the Upper Gastrointestinal Tract. The Upper Gastrointestinal Tract includes but is not restricted to, the organs; tissues; and subsystems: Esophagus, Stomach, Duodenum, Small Bowel, and underlying areas. The instrument is introduced per orally when indications consistent with the requirement for the procedure are observed in Adult and Pediatric patient populations.

Comparison To Predicated Device(s):

The submission for substantial equivalence included FG-36UX literature including specifications, the identification of standard set components, and identification of optional accessories, comparison tables were provided to illustrate the comparisons to the predicated devices in summary. The submission for substantial equivalence was not based on an assessment of clinical performance data.

Prepared by: Paul Silva Signature: Paul Silva Date: 03.09.01